

fifth line from last, after "triglycerides"  
insert ✓ a comma -- , --.

N/E Page 16, seventh line after Table 10, correct the  
spelling of -- disease.--.

✓  
Page 17, second line, after "to" insert -- the --;  
eighth line from last, after "to" insert  
-- the --; and  
third line from last, after "to" insert -- the  
--.

✓  
Page 18, ninth line from last, change "carrier" to  
--carriers--.

✓  
Page 19, first line after the Example table, change  
"weighted" to read -- weighed --; and  
next to last line, delete the comma.

IN THE CLAIMS:

Cancel Claims 1-15.

Please enter the following new claims:

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-- 16. A method for elevating the HDL  
cholesterol level in the serum of a human patient, which  
comprises administering to the patient a pharmaceutical  
composition in which the active ingredients consist  
essentially of a mixture of fatty acids of which at least 80%  
by weight is comprised of a combination of (all-Z omega-3)-

Contd.

§1

5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) in a weight ratio of EPA:DHA of from 1:2 to 2:1, said composition being administered in amounts providing a daily dosage of 1 to 10 grams of said mixture of fatty acids.

2<sup>17</sup>. The method of claim 1<sup>6</sup>, wherein at least 85% by weight of the mixture of fatty acids is comprised of long chain omega-3 fatty acids.

3<sup>18</sup>. The method of claim 2<sup>17</sup>, wherein the EPA constitutes 40 to 60% by weight of the mixture of fatty acids and the DHA constitutes 25 to 45% by weight of the mixture of fatty acids.

4<sup>19</sup>. The method of claim 3<sup>18</sup>, wherein the EPA and DHA are present in the composition in an EPA:DHA weight ratio of from 1:1 to 2:1.

9<sup>20</sup>. The method of claim 4<sup>19</sup>, wherein at least 4.5% by weight of the mixture of fatty acids is comprised of fatty acids other than EPA and DHA that have 20, 21, or 22 carbon atoms.

5<sup>21</sup>. The method of claim 9<sup>20</sup>, wherein at least 3% by weight of the mixture of fatty acids is comprised of omega-3 fatty acids other than EPA and DHA that have 20, 21, or 22 carbon atoms.

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22. The method of claim 19, wherein at least 1% by weight of the mixture of fatty acids is comprised of (all-Z omega-3)-6,9,12,15,18-heneicosapentaenoic acid.

10 23. The method of any of claims 20, 21, or 22, wherein the fatty acids are present in the composition in esterified form.

11 24. The method of any of claims 20, 21, or 22, wherein the fatty acids are present in the composition in ethyl ester form.

12 25. The method of any of claims 20, 21, or 22, wherein the fatty acids are present in the composition in salt form.

13 26. The method of any of claims 20, 21, or 22, wherein the fatty acids are present in the composition in the free acid form.

7 27. The method of claim 22, wherein at least 85% by weight of the fatty acid content of the composition is comprised of the combination of EPA and DHA, and the fatty acids are present in the composition in ethyl ester form.

8 28. The method of claim 19, wherein the composition is administered orally.

29. A method for the treatment or prophylaxis of hypertension in an adult human patient, which comprises

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*§1*

administering to the patient, on a daily basis, an effective amount of a pharmaceutical composition in which the active ingredients consist essentially of a mixture of fatty acids of which at least 80% by weight is comprised of a combination of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) in a weight ratio of EPA:DHA of from 1:2 to 2:1.

30. The method of claim 29, wherein at least 85% by weight of the mixture of fatty acids is comprised of long chain omega-3 fatty acids.

31. The method of claim 30, wherein the EPA constitutes 40 to 60% by weight of the mixture of fatty acids and the DHA constitutes 25 to 45% by weight of the mixture of fatty acids.

32. The method of claim 31, wherein the EPA and DHA are present in the composition in an EPA:DHA weight ratio of from 1:1 to 2:1.

33. The method of claim 32, wherein at least 3% by weight of the mixture of fatty acids is comprised of omega-3 fatty acids other than EPA and DHA that have 20, 21, or 22 carbon atoms.

34. The method of claim 33, wherein at least 90% by weight of the composition is comprised of long chain, polyunsaturated, omega-3 fatty acids.

35. The method of claim 34, wherein at least 1% by weight of the mixture of fatty acids is comprised of (all-Z omega-3)-6,9,12,15,18-heneicosapentaenoic acid.

36. The method of any of claims 33, 34, or 35, wherein the fatty acids are present in the composition in esterified form.

37. The method of any of claims 33, 34, or 35, wherein the fatty acids are present in the composition in ethyl ester form.

38. The method of any of claims 33, 34, or 35, wherein the fatty acids are present in the composition in the free acid form.

39. The method of claim 35, wherein at least 85% by weight of the fatty acid content of the composition is comprised of the combination of EPA and DHA, and the fatty acids are present in the composition in ethyl ester form.

40. The method of claim 32, wherein the composition is administered orally.

41. A method for the treatment or prophylaxis of multiple risk factors for cardiovascular diseases, which comprises administering to a patient a mixed-fatty acids composition in which

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*B1*

a) at least 80% by weight of the composition  
is comprised of omega-3 fatty acids,

b) at least 80% by weight of the total fatty acid content of the composition is comprised of a combination of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) in a weight ratio of EPA:DHA of from 1:2 to 2:1, and

c) the fatty acids are in admixture with a pharmaceutically acceptable carrier.

42. A method for the treatment or prophylaxis of multiple risk factors for cardiovascular diseases in an adult human patient, which comprises orally administering to the patient a pharmaceutical composition in which the active ingredients consist essentially of a mixture of fatty acids of which at least 80% by weight is comprised of a combination of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) in a weight ratio of EPA:DHA of from 1:2 to 2:1, said composition being administered in amounts providing a daily dosage of 1 to 10 grams of said mixture of fatty acids.

43. The method of claim 42, wherein at least 85% by weight of the mixture of fatty acids is comprised of long chain omega-3 fatty acids.

44. The method of claim 43, wherein the EPA constitutes 40 to 60% by weight of the mixture of fatty acids

*Contd.*

B1 and the DHA constitutes 25 to 45% by weight of the mixture of fatty acids.

45. The method of claim 44, wherein the EPA and DHA are present in the composition in an EPA:DHA weight ratio of from 1:1 to 2:1.

46. The method of claim 45, wherein at least 4.5% by weight of the mixture of fatty acids is comprised of fatty acids other than EPA and DHA that have 20, 21, or 22 carbon atoms.

47. The method of claim 45, wherein at least 3% by weight of the mixture of fatty acids is comprised of omega-3 fatty acids other than EPA and DHA that have 20, 21, or 22 carbon atoms.

48. The method of claim 45, wherein at least 1% by weight of the mixture of fatty acids is comprised of (all-Z omega-3)-6,9,12,15,18-heneicosapentaenoic acid.

49. The method of any of claims 46, 47, or 48, wherein the fatty acids are present in the composition in esterified form.

50. The method of any of claims 46, 47, or 48, wherein the fatty acids are present in the composition in ethyl ester form.

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51. The method of any of claims 46, 47, or 48,  
wherein the fatty acids are present in the composition in  
salt form.

52. The method of any of claims 46, 47, or 48,  
wherein the fatty acids are present in the composition in the  
free acid form.

14 53. A pharmaceutical mixed-fatty-acids composition  
in which

a) at least 80% by weight of the composition  
is comprised of a combination of (all-Z omega-3)-  
5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-  
4,7,10,13,16,19-docosahexaenoic acid (DHA) in a weight ratio  
of EPA:DHA of from 1:2 to 2:1 and

b) (all-Z omega-3)-6,9,12,15,18-  
heneicosapentaenoic acid is present in an amount of at least  
one percent by weight.

15 54. The composition of claim 53, wherein at least  
85% by weight of the composition is comprised of long chain  
omega-3 fatty acids.

16 55. The composition of claim 54, wherein the EPA  
constitutes 40 to 60% by weight of the composition and the  
DHA constitutes 25 to 45% by weight of the composition.

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56. The composition of claim 55, wherein C 20:4 omega-6 fatty acid constitutes at least one percent by weight of the composition.

18 19

57. The composition of claim 56, wherein C 22:5 omega-3 fatty acid constitutes at least one percent by weight of the composition.

19 20

58. The composition of claim 55, wherein the (all-Z omega-3)-6,9,12,15,18-heneicosapentaenoic acid is present in an amount of from 1 to 4% by weight.

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59. The composition of claim 58, wherein C 22:5 omega-3 fatty acid constitutes 1 to 3% by weight of the composition.

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60. The composition of any of claims 53, 54, or 55, wherein the EPA and DHA are present in an EPA:DHA weight ratio of from 1:1 to 2:1.

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20 18

61. The composition of any of claims 56, 57, or 58, wherein the EPA and DHA are present in an EPA:DHA weight ratio of from 1:1 to 2:1.

22 62  
28 63

62. The composition of claim 59, wherein the EPA and DHA are present in an EPA:DHA weight ratio of from 1:1 to 2:1.

63. A pharmaceutical mixed-fatty-acids composition in which

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a) at least 80% by weight of the composition  
is comprised of a combination of (all-Z omega-3)-  
5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-  
4,7,10,13,16,19-docosahexaenoic acid (DHA) in a weight ratio  
of EPA:DHA of from 1:2 to 2:1 and

b) at least 3% by weight of the composition  
is comprised of omega-3 fatty acids other than EPA and DHA  
that have 20, 21, or 22 carbon atoms.

29 64. The composition of claim 63, wherein 3 to 5%  
by weight of the composition is comprised of omega-3 fatty  
acids other than EPA and DHA that have 20, 21, or 22 carbon  
atoms.

30 65. The composition of claim 63, wherein at least  
85% by weight of the composition is comprised of long chain  
omega-3 fatty acids.

31 66. The composition of claim 65, wherein the EPA  
constitutes 40 to 60% by weight of the composition and the  
DHA constitutes 25 to 45% by weight of the composition.

38 67. The composition of claim 66, wherein (all-Z  
omega-3)-6,9,12,15,18-heneicosapentaenoic acid is present in  
an amount of at least one percent by weight.

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68. The composition of claim ~~31~~ 68, wherein C 20:4 omega-6 fatty acid constitutes at least one percent by weight of the composition.

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69. The composition of claim ~~31~~ 69, wherein C 22:5 omega-3 fatty acid constitutes at least one percent by weight of the composition.

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70. The composition of claim ~~31~~ 67, wherein the (all-Z omega-3)-6,9,12,15,18-heneicosapentaenoic acid is present in an amount of from 1 to 4% by weight.

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71. The composition of claim ~~31~~ 69, wherein C 22:5 omega-3 fatty acid constitutes 1 to 3% by weight of the composition.

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72. The composition of any of claims ~~31~~ 63, ~~33~~ 65, or ~~31~~ 66, wherein the EPA and DHA are present in an EPA:DHA weight ratio of from 1:1 to 2:1.

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73. The composition of any of claims ~~31~~ 61, ~~33~~ 68, or ~~31~~ 69, wherein the EPA and DHA are present in an EPA:DHA weight ratio of from 1:1 to 2:1.

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74. The composition of claim ~~31~~ 71, wherein the EPA and DHA are present in an EPA:DHA weight ratio of from 1:1 to 2:1.

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75. The composition of any of claims ~~31~~ 63, ~~33~~ 68, or ~~31~~ 74, wherein the composition is in oral dosage form.

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26. The composition of any of claims ~~63, 66~~, or  
74, wherein the fatty acids are present in esterified form.

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27. The composition of any of claims ~~63, 66~~, or  
74, wherein the fatty acids are present in ethyl ester form.

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28. The composition of any of claims ~~63, 66~~, or  
74, wherein the fatty acids are present in salt form.

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29. The composition of claim ~~44~~, wherein the fatty  
acids are present in the free acid form.

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30. The composition of claim ~~49~~, wherein the fatty  
acids are present in the free acid form.<sup>6631</sup>

34

31. The composition of claim ~~52~~, wherein the fatty  
acids are present in the free acid form.<sup>7433</sup>

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32. A mixed-fatty-acids composition for the  
treatment or prophylaxis of multiple risk factors for  
cardiovascular diseases in which

a) at least 80% by weight of the composition  
is comprised of a combination of (all-Z omega-3)-  
5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-  
~~4,7,10,13,16,19~~-docosahexaenoic acid (DHA) in a weight ratio  
of EPA:DHA of from 1:2 to 2:1 and

b) at least 3% by weight of the composition  
is comprised of omega-3 fatty acids other than EPA and DHA  
that have <sup>20</sup>  
<sup>18</sup>, 21, or 22 carbon atoms.

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83. The composition of claim 82, wherein 3 to 5%  
B1 by weight of the composition is comprised of omega-3 fatty  
acids other than EPA and DHA that have 20, 21, or 22 carbon  
atoms.

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49 84. A pharmaceutical mixed-fatty-acids composition  
in which

- a) at least 90% by weight of the composition  
is comprised of long chain, polyunsaturated, omega-3 fatty  
acids;
- b) at least 80% by weight of the composition  
is comprised of a combination of (all-Z omega-3)-  
5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-  
4,7,10,13,16,19-docosahexaenoic acid (DHA) in a weight ratio  
of EPA:DHA of from 1:1 to 2:1, with the EPA constituting 40  
to 60% by weight of the composition and the DHA constituting  
25 to 45% by weight of the composition;
- c) at least 4.5% by weight of the  
composition is comprised of omega-3 fatty acids other than  
EPA and DHA that have 20, 21, or 22 carbon atoms;
- d) from 1 to 4% by weight of the composition  
is comprised of (all-Z omega-3)-6,9,12,15,18-  
heneicosapentaenoic acid; and
- e) the composition is in oral dosage form  
and includes an effective amount of a pharmaceutically  
acceptable antioxidant.

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50 85. The composition of claim 84, wherein the fatty acids are present in ethyl ester form.

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52 86. The composition of claim 85, wherein at least 85% by weight of the fatty acid content of the composition is comprised of the combination of EPA and DHA.

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87. The composition of either of claims 85 or 86, wherein the antioxidant is tocopherol.

24 53

88. A mixed-fatty-acids composition for the treatment or prophylaxis of multiple risk factors for cardiovascular diseases in which

- a) at least 80% by weight of the composition is comprised of omega-3 fatty acids,
- b) at least 80% by weight of the total fatty acid content of the composition is comprised of a combination of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) in a weight ratio of EPA:DHA of from 1:2 to 2:1, and
- c) omega-3 fatty acids other than EPA and DHA are present in an amount of at least 1.5% by weight of the total fatty acids.

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89. The composition according to claim 88, wherein other long chain fatty acids present are selected from the group consisting of (all-Z omega-3)-6,9,12,15,18-heneicosapentaenoic acid, (all-Z omega-3)-7,10,13,16,19-

*Contd.*

*81* docosapentaenoic acid, and (all-Z omega-3)-6,9,12,15-octadecatetraenoic acid.

*25/ft* *54* *53/24* 90. The composition according to claim *88* or claim *89*, wherein the total concentration of long chain omega-3 fatty acids is at least 90% by weight, the combined weight of the EPA and DHA constitutes at least 85% by weight of the total fatty acids, the EPA and DHA are present in a weight ratio of EPA:DHA of from 1:1 to 2:1, and the other long chain omega-3 C 20, C 21 and C 22 acids constitute at least 4.5% by weight of the composition.

*57* *91* *53/24* 91. The composition according to claim *88*, wherein the total concentration of long chain omega-3 fatty acids is at least 95% by weight, the combined weight of the EPA and DHA constitutes at least 90% by weight of the total fatty acids, and the other long chain C 20, C 21 and C 22 acids constitute at least 4.5% by weight of the composition.

*25/ft* *59* *53/24* 92. The composition according to claim *88* or claim *89*, wherein the total concentration of long chain omega-3 fatty acids is at least 85% by weight and the other long chain C 20, C 21 and C 22 acids constitute at least 4.5% by weight of the composition.

*58* *93* *57* 93. The composition according to claim *91*, wherein EPA and DHA are present in a weight ratio of EPA:DHA of from 1:1 to 2:1.

*(40)* 94. The composition according to claim 88, wherein  
the fatty acids are present in the form of pharmaceutically  
acceptable salts.

*(61)* 95. The composition according to claim 88, wherein  
the fatty acids are present in the form of an ester.

*(62)* 96. The composition according to claim 95, wherein  
the fatty acids are present in the form of ethyl esters.

*(63)* 97. The composition according to claim 95, wherein  
the ester is an alkyl ester.

*24 53* *53 24* 98. The composition of any of claims 53, 62, or  
88, wherein the composition is in oral dosage form.

*25 54* *54* 99. The composition of any of claims 53, 62, or  
89, wherein the fatty acids are present in esterified form.

*25 54* *26* 100. The composition of any of claims 53, 62, or  
89, wherein the fatty acids are present in ethyl ester form.

*55* 101. The composition of claim 89, wherein the fatty  
acids are present in salt form.

*25 54* *27* 102. The composition of any of claims 53, 62, or  
89, wherein the fatty acids are present in the free acid  
form. --